

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111
Serial Number: 09/847061
Filing Date: May 1, 2001
Title: POLYHYDROXY GLYCOPEPTIDE DERIVATIVES

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REMARKS

Reconsideration and withdrawal of the rejections of the claims in view of the amendments and remarks presented herein is respectfully requested. Claims 7 and 20 have been amended; claims 1-6, 8-12 and 15 have been cancelled without prejudice or disclaimer; and claims 16-17 have been withdrawn from consideration by the Examiner. Thus, claims 7, 13-14 and 16-28 are pending.

Claim 20 and the Specification have been amended as suggested by the Examiner at page 4 of the Office Action.

The 35 U.S.C. § 101 Rejection of the Claims

The Examiner rejected claim 7 under 35 U.S.C. § 101, asserting that the claimed glycopeptide is not distinguished from naturally existing products. This rejection is respectfully traversed.

Claim 7 is directed to a glycopeptide of formula II, comprising, *inter alia*, a side chain R^{20} , wherein R^{20} is $-CH_2-CH(OH)CH(OH)CH_2-Y-R^b-(Z)_x$ or $-CH_2-CH(OH)CH(OH)CH_2-R^{17}$. There is no evidence of record that glycopeptides having the recited side chain are found in nature, and Applicants are not aware of any naturally occurring glycopeptides possessing the R^{20} side-chain recited in the claims. Accordingly, the Examiner has not met the burden required to establish or support a rejection under 35 U.S.C. § 101. Withdrawal of the rejection is respectfully requested.

The 35 U.S.C. § 112, Second Paragraph, Rejection of the Claims

The Examiner rejected claims 7, 13-14 and 18-28 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, the Examiner asserts that the phrases "x is 1 or 2" and "or a pharmaceutically acceptable salt, stereoisomer, or prodrug thereof" renders claim 7 (and dependent claims 13-14 and 18-28) indefinite. Claim 7 has been amended to no longer recite the term "prodrug." As this rejection may be maintained with respect to the pending claims, it is respectfully traversed.

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Regarding the phrase "x is 1 or 2," the Examiner's attention is respectfully directed to claim 7, wherein R^{20} is defined as $-CH_2-CH(OH)CH(OH)CH_2-Y-R^b-(Z)_x$ or $-CH_2-CH(OH)CH(OH)CH_2-R^{17}$ (emphasis added). Since the group "x" is recited and properly defined in the claim, withdrawal of the rejection of claim 7 under 35 U.S.C. § 112, second paragraph, to the extent that it relates to the recitation of "x is 1 or 2," is requested.

With respect to the phrase "or a pharmaceutically acceptable salt or stereoisomer thereof" as recited in amended claim 7, the Examiner is urged to consider that these terms are conventionally used and well understood in the art. In addition, the specification discloses that the phrase "pharmaceutically acceptable salt" refers to a salt that retains the biological effectiveness and properties of a parent compound and is not biologically or otherwise harmful if administered (page 31, lines 10-14). In addition, the specification identifies a number of both pharmaceutically acceptable base addition salts and pharmaceutically acceptable acid addition salts (page 31, line 15-page 16, line 7). In light of the conventional use of the term in the art and the general guidance provided in the specification, it is respectfully submitted that the metes and bounds of the term "a pharmaceutically acceptable salt thereof" would be readily understood by one skilled in the art.

With respect to the term "stereoisomer," it is also submitted that the meaning of this term is well understood in the relevant field. Additionally, even if the metes and bounds of the term "stereoisomer" was not readily understood by one skilled in the art, *arguendo*, the specification discloses that a stereoisomer refers to a compound having the same molecular formula as a given compound, wherein the atoms of the stereoisomer differ from the atoms of the given compound in the way that the atoms of the stereoisomer are oriented in space, but wherein the atoms in the stereoisomer are like the atoms in the given compound with respect to which atoms are joined to which other atoms (page 27, lines 12-18). In light of this disclosure, the metes and bounds of the term "a stereoisomer thereof," as recited in the instant claims, would be readily understood by one skilled in the art.

Therefore, it is respectfully submitted that, to the extent that it relates to the phrase "or a pharmaceutically acceptable salt or stereoisomer thereof," withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, is appropriate and is respectfully requested.

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Conclusion

Applicants respectfully submit that the claims (7, 13-14 and 16-28) are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicants' attorney at (612) 359-3265 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743

Respectfully submitted,


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By their Representatives,

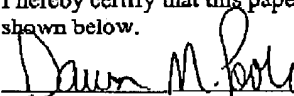
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